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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/036,681

11/08/2001

David G. Barkalow

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01/19/2005

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/036,681	BARKALOW ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Humera N. Sheikh	1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-19 and 25-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-19 and 25-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Amendment and Applicant's Arguments/Remarks, both filed 11/01/04 is acknowledged.

Claims 16-19 and 25-46 are pending. Claims 16, 19, 25 and 41 have been amended. Claims 1-15 and 20-24 have previously been cancelled. New claims 44-46 have been added.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 16-19, 25-39 and 41-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers (US Pat. No. 5,433,960).**

Meyers teaches an edible film composition comprising edible *film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, starches, dextrans, maltodextrans, etc. and *combinations thereof* including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%) wherein the edible film composition also comprises at least one or more active agents located in the edible film, which include *dental agents* (i.e., plaque pH buffers/inhibitors, minerals, antimicrobial agents, microbial inhibitors,

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phosphates); flavor enhancers, sweeteners, softeners and antioxidants (see reference column 3, line 15 thru col. 14, line 18); (col. 6, line 20 thru col. 11, line 55) and claims.

Meyers teaches that suitable water-soluble film forming agents include, besides from the celluloses and starches, edible polymers, edible plastics, low calorie bulking agents, vegetable gums, such as guar gum, locust bean gum, carrageenan gum, alginates, etc. The preferred water-soluble film forming agents are cellulose derivatives, which include ethyl cellulose, methyl cellulose, hydroxypropyl cellulose and sodium hydroxymethyl cellulose. The film-forming agent can be used in amounts of about 5% to about 25% (col. 6, lines 20-50). The ranges of film-forming agents taught by Meyers are overlapping ranges (instant range – ~10 - ~90%).

Bulk fillers, such as calcium carbonate, magnesium carbonate, talc and dicalcium phosphate are disclosed in amounts of between 5-95% at col. 9, lines 14-22.

According to Meyers, plasticizers are added to improve the flexibility of the film. Plasticizers mentioned herein include glycerin, polyethylene glycol (PEG), polyols and hydrogenated starch hydrolysates. The plasticizer may be contained in amounts of about 0.5-15% (instant range - <20%) (col. 8, line 7 thru col. 10, line 30).

Additionally, at least one or more active agents are included in the edible film forming composition, as delineated above.

This rejection is maintained and applied to newly added claims 44-46. Meyers teaches an edible film composition comprising edible film-forming agents consisting of celluloses, cellulose derivatives, starches, dextrans, maltodextrins, etc. and combinations thereof. Meyers teaches film-forming agents of cellulose derivatives, which include ethyl cellulose, methyl cellulose, hydroxypropyl cellulose and sodium hydroxymethyl cellulose. Plasticizers, flavor enhancers,

sweeteners, softeners and antioxidants are also included in the edible film of Meyers for enhanced properties.

**Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers (US Pat. No. 5,433,960) in view of Zerbe *et al.* (US Pat. No. 5,948,430).**

Meyers, as discussed above, teaches an edible film composition comprising edible *film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, starches, dextrans, maltodextrins, etc. and *combinations thereof* including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%).

Meyers teaches the use of various acids at col. 8, lines 5-11. Meyers is deficient only in the sense that he does not teach an acid from the selective group of claim 40.

**Zerbe *et al.*** teach a water-soluble film composition for oral administration comprising film-forming agents, fillers, plasticizers and flavor-enhancing acids, wherein suitable acids include tartaric acid and citric acid (col. 2, line 1 thru col. 3, line 40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Zerbe *et al.* within Meyers, because Zerbe *et al.* explicitly teach a water-soluble film forming composition comprising cosmetically active agents such as flavor-enhancing acids (i.e., tartaric, citric) to impart an enhancement of flavor to the composition and similarly, Meyers teaches an edible water-soluble film forming composition comprising active agents that include flavor enhancers and discloses various acids (i.e., stearic,

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lauric, palmitic, arachidic, oleic, linoleic and eladic acids). The expected result would be an edible film-forming composition capable of imparting enhancement of flavors and freshness of the mouth, as similarly desired by the Applicant.

### ***Response to Arguments***

Applicant's arguments filed 11/01/04 have been fully considered but they are not persuasive.

Applicant argued, "Meyers and Zerbe, either alone or in combination, do not disclose a pullulan-free stand alone edible film having similar properties as a pullulan-based edible film as recited in the present claims. Meyers discloses a chewing gum coating. The Meyers coating requires a support substrate upon which to be applied, the support substrate being a chewing gum piece. Meyers has no disclosure whatsoever that the coating may stand alone or is otherwise self-supporting. Similarly, the Zerbe composition requires a carrier substrate for support. The instant 'stand alone' film does not include pullulan-like ingredients or other expensive support ingredients. Meyers and Zerbe have no disclosure regarding 1) a stand alone film and 2) a pullan-free film with film properties similar to a pullulan-based edible film."

These arguments have been carefully considered but were not found persuasive. Applicant's arguments of a 'stand alone' edible film is not persuasive since the Examiner notes that the instant claims utilize "comprising" claim language, and thus the "comprising" claim language permits the use of additional ingredients besides from those recited in the instant claims. Additional ingredients, in this instance, could be structural support ingredients, such as those

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taught by Meyers and Zerbe et al. Regarding the instant 'pullulan-free' film limitation, Meyers, while suggesting that a 'great number of ingredients are envisioned', of which pullulan is included, does not teach or suggest that pullulan is a mandatory component. Furthermore, the Examiner points out that Examples 1-11 of Meyers do not include any pullulan, rendering the film 'pullulan-free'. Applicant's arguments that Meyers and Zerbe do not disclose a pullulan-free stand alone edible film having similar properties as a pullulan-based edible film is not persuasive since the properties desired by Applicants, such as properties of 'flexibility, non-hygroscopicity, mouthfeel and dissolution rate' (instant claim 46) are explicitly taught and suggested in the prior art film formulations. Meyers teaches the incorporation of plasticizers & softeners (for flexibility), flavor enhancers & sweeteners (mouthfeel), antioxidants, emulsifiers and the like (see, for instance, col. 9 line 23 – col. 10, line 17). Thus, since the prior art teaches the incorporation of the ingredients (i.e., plasticizers, flavorants, etc) in a film formulation, the properties imparted by those ingredients would also be the same as claimed by Applicant. Moreover, Applicants have not demonstrated any unusual or unexpected results that accrue from the instant inventions' components or properties. The prior art teaches a similar composition, an edible film composition, comprising the same ingredients for use in the same field of endeavor as the Applicants, and thus the properties and benefits attributed by those ingredients would also be the same as those claimed. Thus, for the reasons advanced above, the instant invention is rendered *prima facie* obvious over the prior art of record.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh 

Patent Examiner

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January 13, 2005

  
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